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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,020	06/23/2004	Yutaka Ashida	AIA-107-PCT	2767

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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,020	ASHIDA ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *4-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Claims 1 and 17 amended by Applicant and received on 10 April 2005.

Claims 13 and 24-53 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

Currently, Claims 1-3 and 17 are under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Amendment

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 10 April 2005, with respect to the rejection of claims 1-3 and 17 under Longley (A*, US Patent Number: 6,576,812 B1), in view of Zsebo (B*, US Patent Number: 6,204,363 B1), is withdrawn in view of priority claimed by Applicant, which now renders the reference by Longley, which was published 06/2003, invalid. Please note, the original rejection made on the original Claim 1, which read "A screening method for active ingredients which exhibit effects of ameliorating pruritus, rough skin or sensitive skin, or effects of skin whitening, by inhibiting production and/or release of stem cell factor (SCF), the method being characterized by comprising the steps of contacting SCF-expressing cells with test ingredients, assaying the amount of SCF produced

and/or released by said cells and selecting test ingredients which reduce the amount of production and/or release of SCF as said active ingredients, wherein said SCF-expressing cells are subjected to stimulation to promote SCF production and/or release and newly amended claim 1 would have been unpatentable Longley (A*), in view of Zsebo (B*), as would have both new and amended Claims 2, 3 and 17 if the reference date were valid. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Kawaguchi et al (U, J. Invest. Dermatol. 2001; 116(6): 920-925), in view of Botchkareva et al. (V, FASEB 2001; 15: 645-658).

Claim Rejections - 35 USC § 103

Claims 1-3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hachiya et al. (U, J. Invest. Dermatol. 2001; 116(6): 578-586), Kawaguchi et al (U, J. Invest. Dermatol. 2001; 116(6): 920-925), in view of Botchkareva et al. (V, FASEB 2001; 15: 645-658). Newly applied as necessitated by amendment.

Applicant argues that use of a transgenic mouse to screen out a potentially active compound is expensive and not preferable from the standpoint of protecting animals. Applicant's arguments have been fully considered but they are not persuasive. Use of transgenic animals in certain assays is viewed as preferable by those conducting the tests regardless of whether the use of such animals is cost effective or whether the use of animals in general for testing is humane. Please note that Applicant was originally claiming **any** SCF-expressing cell and is now claiming **any** epidermal keratinocyte.

Applicant further discloses that the SCF-producing cells used may be human or other mammalian cells, and for example, they may be keratinocytes, fibroblasts, vascular endothelial cells, etc. derived from a rat, mouse, rabbit or the like (See paragraph 0044).

Hachiya teaches a method for first measuring the amount of stem cell factor (SCF), in human keratinocytes and observing the effect of UV irradiation on SCF, which is released by keratinocytes, which was found to activate c-kit expression in keratinocytes and melanocytes following UV exposure (see page 579). Hachiya further teaches a method for injecting dark guinea pig skin, as a model for human skin, with ACK2 (a c-kit function blocker) after exposure of the guinea pig to UVB irradiation (See page 580). Hachiya further teaches that after injection of the guinea pig with ACK2, ACK2 was found to abolish the UVB-induced pigmentation and color of the skin injected was similar to that not exposed to UVB irradiation and that interruption of SCF binding to receptor c-kit with c-kit inhibitory antibodies, such as ACK2, decreases the number, size and dendricity of melanocytes and that incomplete inhibition of pigmentation observed following the blockage of SCF-c-kit binding is due to an essential role of SCF-c-kit signaling (See page 584).

Kawaguchi teaches a method for determining the effect of monoclonal antibody ACK45 on Kit receptors (which are receptor type tyrosine kinase and which play an important role in melanocyte development) and on the increase of $Mitf^+$, $TRP\text{-}1^+$ and $Dopa^+$ cells by injecting murine epidermal sheets (please note that epidermal tissue comprises 90% keratinocyte) with monoclonal antibody ACK45 after observing the effect of UV irradiation on its ligand, stem cell factor (SCF), which is released by

keratinocytes and which activates Kit receptor on melanocyte precursors following UV exposure (See page 920, 922 and 924), which reads on a screening method for active ingredients which exhibit effects of skin whitening by inhibiting production and/or release of stem cell factor, wherein keratinocytes are contacted with test ingredients, the amount of SCF produced/released is assayed and a test ingredient is selected, wherein SCF-expressing cells are subjected to ultraviolet irradiation.

Botchkareva teaches that in mice, melanocytes progressively disappear from the epidermis shortly after birth and are present only in the stem cell factor and c-kit map to the steel and the dominant white spotting loci and mutations in these genes result in unpigmented hairs, suggesting that the SCF/c-kit signaling is required for maintenance of HF melanocytes (See page 646). Botchkareva further teaches that in order to determine the dependence on SCF of the melanogenically active follicular melanolcytes, ACK45 was administered intradermally and after several days of administration of ACK45, ACK45-treated mice had white, depigmented hairs (indicating the absence of melanin), whereas untreated mice had black hairs. Botchkareva further teaches that SCF/c-kit signaling is required for melanocyte proliferation, which was determined by studying SCF (See pages 652 and 654). Botchkareva further teaches that blocking SCF/c-kit signaling during one hair cycle only affects that cycle. Botchkareva further teaches that if no ACK45 is administered to a mouse previously receiving the ACK45 injections upon the beginning of the next hair cycle, the hair grows in black (See page 654).

The teachings of Hachiya, Kawaguchi and Botchkareva are set forth above. Hachiya does not teach the method steps in the order as claimed of inhibiting production and/or release of stem cell factor, the method being characterized by comprising the steps of contacting stem cell factor-expressing cells with test ingredients, assaying the amount of stem cell factor produced and/or released by said cells and selecting test ingredients which reduce the amount of production and/or release of stem cell factor as said active ingredients, wherein said SCF-expressing cells are subjected to stimulation to promote stem cell factor production and/or release in this order. However, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to employ the method taught by Hachiya to determine the amount of production and/or release of stem cell factor to provide the instantly claimed invention because at the time the invention was made, measuring the level of stem cell factor affected by UV irradiation and studying the effects of an antibody is a good measurement of the effect of a compound on treating a disorder, where decreased SCF is desired, was well known in the art, as clearly taught by Kawaguchi, as was the skin whitening effect of ACK45, as clearly taught by Botchkareva.

Based upon the beneficial teachings of the cited reference, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Regarding the specific order of the method steps in claims 3 and 17, it would have been obvious to practice the method steps made obvious by the teaching of the

cited reference in either order because both Hachiya and Kawaguchi teach the method as comprising those steps and one of ordinary skill in the art would have practiced those steps in either order. One of ordinary skill in the art would be able to determine that changing the order of the method steps could potentially lead to different compounds, however, the effect of the compound on treating skin disease, wherein the compound specifically targets the epidermal stem cell factor or its receptor, is the same.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark
AU 1655

Amy L. Clark
June 19, 2006

Michele C. Flood.
MICHELE FLOOD
PRIMARY EXAMINER